

Notice of Allowability

Application No.

09/922,549

Examiner

Laura McGillem

Applicant(s)

RAPP, JEFFREY C.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/29/2006.
2. ☒ The allowed claim(s) is/are 217-250.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>11/9/06</u> |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

It is noted that claims 1-216 have been canceled and claims 217-250 have been added in the amendment filed on 8/29/2006.

Claims 217-250 are directed to allowable products. Pursuant to the procedures set forth in MPEP § 821.04(B), claims directed to combinations and processes comprising or using the avian lysozyme expression control region commensurate in scope with the instant claims, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. A restriction requirement was mailed on 12/11/2002 requiring restriction among Groups I-VI, drawn to a nucleic acid comprising an avian lysozyme expression control region, *in vivo* and *in vitro* methods of expression of a polypeptide, *in vivo* and *in vitro* transformed cells and a transgenic avian. During the course of prosecution each of these claims have been canceled. Instant claims 217-250 are now drawn to isolated DNA molecules comprising a nucleic acid comprising an avian lysozyme expression control region operably linked to a polynucleotide encoding a polypeptide and an expression vector comprising a nucleic acid comprising an avian lysozyme expression control region.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 12/11/2002 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim

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presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kyle Yesland on 11/9/2006.

The application has been amended as follows:

In the Claims:

217. An isolated recombinant DNA molecule comprising an avian lysozyme gene expression controlling region which comprises a nucleotide sequence at least 95% identical to the full length of SEQ ID NO:67.

218. The isolated DNA molecule of claim 217 wherein the nucleotide sequence is at least 99% identical to the full length of SEQ ID NO: 67.

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219. The isolated DNA molecule of claim 217 wherein the nucleotide sequence is the full length of SEQ ID NO: 67.

231. An isolated recombinant DNA molecule comprising a nucleotide sequence at least 95% identical to the full length of SEQ ID NO: 67 operably linked to a polynucleotide encoding a polypeptide.

232. The isolated DNA molecule of claim 231 wherein the nucleotide sequence is at least 99% identical to the full length of SEQ ID NO: 67.

233. The isolated DNA molecule of claim 231 wherein the nucleotide sequence is the full length of SEQ ID NO: 67.

243. An isolated recombinant DNA molecule comprising a nucleotide sequence at least 95% identical to the full length of SEQ ID NO:67 operably linked to a nucleotide sequence encoding a protein of pharmaceutical interest.

244. The isolated DNA molecule of claim 244 243 wherein the nucleotide sequence is at least 99% identical to the full length of SEQ ID NO:67.

245. The isolated DNA molecule of claim 244 243 wherein the nucleotide sequence is the full length of SEQ ID NO:67.

246. An expression vector containing a recombinant DNA molecule comprising an avian lysozyme gene expression controlling region comprising a nucleotide sequence at least 95% identical to the full length of SEQ D NO: 67.

247. The expression vector of claim 246 wherein the nucleotide sequence is at least 99% identical to the full length of SEQ ID NO: 67.

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248. The expression vector of claim 246 wherein the nucleotide sequence is the full length of SEQ ID NO: 67.

249. The expression vector of claim 246 wherein the gene expression controlling region is operably linked to a polynucleotide encoding a heterologous polypeptide.

250. The expression vector of claim 248 249 wherein the heterologous polypeptide is a protein of pharmaceutical interest.

In the Specification:

Abstract, line 1

The invention provides for lysozyme gene expression controlling regions which

Conclusion

Claims 217-250 are allowed (now claims 1-34).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura McGillem, PhD
11/13/2006


DANIEL M. SULLIVAN
PATENT EXAMINER